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PATENT APPLICATION
Docket No. 16778.5a.1.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Ole Thastrup et al.	)
Serial No.:	10/072,036	) Art Unit) 1633
Confirmation No.:	3012	)
Filed:	February 5, 2002	)
For:	A METHOD FOR EXTRACTING QUANTITATIVE INFORMATION RELATING TO AN INFLUENCE ON A CELLULAR RESPONSE	)
Examiner:	M. D. Burkhart	)
Customer No.:	22913	)

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop **APPEAL**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

ARGUMENTS

Reconsideration of the above-referenced application by a panel of examiners is respectfully requested in view of the following remarks. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the clear errors and omissions needed for a *prima facie* rejection.

Applicant respectfully cites to clear error as the Examiner has (1) unreasonably misconstrued the terminology "library of compounds" and "screening a library of compounds," (2) unreasonably misconstrued the Declaration of Dr. Ireland, (3) unreasonably misconstrued the MPEP § 716.01(c) in

dismissing the Declaration of Dr. Ireland, and (4) unreasonably omitted consideration of relevant claim elements.

The Examiner has committed clear error by unreasonably misconstruing[1] the terminology[2] "library of compounds" and "screening a library of compounds" so as to use an overly-broad interpretation of the terminology that is contrary to the understanding of the terminology by one skilled in the art.[3] The Examiner sets forth the following statement on page 4 of the final Office Action:

> the specification provides no definition or guidance as to what constitutes a "library of compounds", hence the term is interpreted ***as broadly reading on a collection of one or more compounds***, e.g. the claim language itself suggests a library comprises "at least one compound" ... a reading of the Ireland declaration reveals nothing more than assertions and the opinion of Mr. Ireland as to the interpretation of the term "library of compounds." (Emphasis added).[4]

Since the Examiner could not find a specific definition in the specification for a "library of compounds" or "screening a library of compounds," the Examiner independently construed the terminology[5, 6] using an overly-broad interpretation. The Examiner does not cite to concrete evidence supporting his alleged definition of "library of compounds"[7] or "screening a library of compounds,"[8] nor does the Examiner appear to understand the meaning of these terms as understood by a skilled artisan. Applicant has submitted the Declaration of Dr. Ireland[9] who is established as one skilled in the art. Dr. Ireland **provided the Examiner with a clear definition for "library of**

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[1] The patented invention, as set forth in the words of the patent claims, must be clearly understood, which is a question of claim construction, or claim interpretation, and it is determined by a court as a matter of law. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S.Ct. 1384 (1996).

[2] The words in a claim are "'generally given their ordinary and customary meaning.'" *Phillips*, 415 F.3d at 1312 (citing *Vitronics*, 90 F.3d at 1582; *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998) ("Absent a special and particular definition created by the patent applicant, terms in a claim are to be given their ordinary and accustomed meaning.")).

[3] Thus, "[t]he inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Phillips*, 415 F.3d at 1313.

[4] Final Office Action mailed June 30, 2007, page 4, 2nd paragraph.

[5] A "library of compounds was over-broadly construed as any "collection of one or more compounds" (e.g., cell culture media and serum). See, Final Office Action mailed June 30, 2007, page 4, 2nd paragraph.

[6] Confirming well-known effects of dexamethasone and serum on a subunit was over-broadly construed as "screening," which is contrary to the concept of "screening" being a process to "determine suitability for a particular purpose or to detect wanted or unwanted attributes." Declaration of Chris M. Ireland, Ph.D., Under 37 C.F.R. § 1.132. See, paragraphs 12-13.

[7] Final Office Action mailed June 30, 2007, page 5, lines 1-13.

[8] Final Office Action mailed June 30, 2007, page 5, line 1 through page 6, line 16.

[9] Declaration of Chris M. Ireland, Ph.D. (who is an independent expert in the field that is neither a named inventor nor affiliated with the assignee), Under 37 C.F.R. § 1.132.

compounds"[10] and "screening a library of compounds,"[11] and declared that *Carey*[12] does not disclose a "library of compounds" or "screening a library of compounds."[13] Thus, the Examiner has **not** interpreted the claimed "library of compounds" and "screening a library of compounds" in a manner known and established by those skilled in the art, but rather has independently and over-broadly interpreted the terminology, the Examiner has committed clear error.

The Examiner has committed clear error by unreasonably misconstruing and rewriting the Declaration of Dr. Ireland. Pages 4-5 of the final Office Action set forth the following:

> Applicants and the Ireland declaration attempt to define "library of compounds" as a collection of compounds that are either pure or at a known concentration ... arranged such that **each compound can be selected from the collection either alone or in combination**. This is unconvincing for two reasons: 1) the claim language (e.g., claim 44) clearly recited using "at least one compound of the library" in step (b) and as such encompasses using only one compound; and , 2) DMEM and FBS, as used by Carey et al, are composed of compounds at known concentrations. (Emphasis added).[14]

The Examiner alleges above that the Declaration states that "**each compound can be selected** from the collection either alone or **in combination**" so that DMEM and/or FBS can be construed to be a "library of compounds." This is not true. The Examiner's alleged definition contradicts the Declaration, which recites "**each compound can be selected from the collection of compounds** for use in an experiment either alone or in combination with other compounds of the library."[15] Under the Declaration, DMEM and/or FBS cannot be considered to be a part of "library of compounds" because **each compound** of DMEM and/or FBS **cannot be selected from the collection of compounds** (i.e., DMEM and/or FBS).[16] The entirety of the Declaration recites that a "library of compounds" requires that each individual compound can be selected alone. However, the individual compounds of DMEM and/or FBS cannot be selected alone. Additionally, the Examiner has neglected to provide any weight to the term "library" in that the "plain meaning of a 'library of compounds' is similar to a standard book library in appearance, function, or organization" such that "a single compound of the collection of compounds can be individually selected for use similar to

[10] Declaration of Chris M. Ireland, Ph.D., Under 37 C.F.R. § 1.132. See, paragraphs 7-10.
[11] Declaration of Chris M. Ireland, Ph.D., Under 37 C.F.R. § 1.132. See, paragraphs 11-14.
[12] Evidence Using a Green Fluorescent Protein-Glucocorticoid Receptor Chimera that the RAN/TC4 GTPase Mediates an Essential Function Independent of Nuclear Protein Import; Carey et al.; *J Cell Biol*, Vol. 133 (1996).
[13] Declaration of Chris M. Ireland, Ph.D., Under 37 C.F.R. § 1.132. See, paragraphs 15-19.
[14] Final Office Action mailed June 30, 2007, page 5, lines 1-13.
[15] Declaration of Chris M. Ireland, Ph.D., Under 37 C.F.R. § 1.132. See, paragraph 10.
[16] Declaration of Chris M. Ireland, Ph.D., Under 37 C.F.R. § 1.132. See, paragraphs 15-18.

how a single book can be selected from a standard book library."[17] Thus, the Examiner has committed clear error by misconstruing and selectively rewriting the definition of the terminology provided in the Declaration.

The Examiner has committed clear error by unreasonably misconstruing and applying MPEP § 716.01(c) in dismissing the Declaration. On page 4 of the final Office Action the Examiner sets forth the following:

> a reading of the Ireland declaration reveals nothing more than assertions and the opinion of Mr. Ireland as to the interpretation of the term "library of compounds." Such opinion evidence is generally not probative when unsupported by facts or evidence, § MPEP 716.01(c).[18]

Section 716.01(c) of the MPEP, as cited by the Examiner, is a rule directed to objective evidence of non-obviousness, which is used to show evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, and allegations that the author(s) of the prior art derived the disclosed subject matter from the Applicant. This section of the MPEP is not directed to the present situation where a skilled artisan has provided dictionary definitions of terms and provided definitions of such terms as understood by a skilled artisan. In fact, the definitions in the Declaration provide citations to **dictionary definitions as evidence of the definition of the terms**, and thereby, the Declaration is supported by facts and evidence. Thus, the Examiner has committed clear error by using MPEP § 716.01(c) to dismiss the Declaration and is otherwise unfounded in dismissing the Declaration.

The Examiner has committed clear error by unreasonably omitting consideration of select elements of the claims. As the Examiner is aware, it is well established that a "claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[19] On page 6 of the final Office Action the Examiner sets forth the following:

> applicants present no reasoning or evidence that the effect of dexamethasone was known on the GR-GFP molecule. Furthermore, because the other compounds used in the methods of Carey et al. did not effect the localization of GR-GFP does not mean they were not screened, it merely means they did not have an effect on GR-GFP localization. This would satisfy the definition of screening compounds as put forth by applicants, i.e., they had "unwanted attributes."[20]

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[17] Declaration of Chris M. Ireland, Ph.D., Under 37 C.F.R. § 1.132. See, paragraphs 7 and 9.
[18] Final Office Action mailed June 30, 2007, page 4.
[19] *Vedegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).
[20] Final Office Action mailed June 30, 2007, page 6.

The Examiner has omitting consideration of the claim element "**subunit** of a component of an intracellular pathway,"[21] and has only considered screening with respect to the entire GR-GFP, which is a hybrid polypeptide with the glucocorticoid receptor ("GR") being the subunit and the Green Fluorescent Protein "GFP" being the luminophore. As such, the Examiner is basing the rejection on the fact that GR-GFP was tested, but not considering that the compositions and/or compounds used in the experiments of *Carey* had well-known effects on the GR (i.e., **subunit**). When the compositions and/or compounds that are tested have well-known effects on the GR, the effects on the subunit (i.e., GR) are not being screened. In fact, *Carey* performs the study to "show that the GR-GFP fusion protein translocates into the nucleus upon exposure to agonist [(Dexamethasone)] with kinetics similar to those published for the glucocorticoid receptor."[22] *Carey* teaches that the compositions and/or compounds that were tested have well-known effects on the GR, and thereby, *Carey* cannot teach "screening the library of compounds **for biological function or biological effect on the subunit** in the one or more cells."[23] One cannot screen a compound for biological function or biological **effect on a subunit** when the compound or library of compounds has a **well-known and documented biological effect on the subunit**. Thus, by omitting consideration of the claim element "**subunit** of a component of an intracellular pathway," the Examiner has committed clear error.

Therefore, due to the aforementioned instances of clear error, the Applicant respectfully requests that the rejection of claims 44-54 be withdrawn.

Dated this 29th day of August, 2007.

Respectfully submitted,

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[21] Presently pending independent claims 44-46 of USSN 10/072,036.
[22] Evidence Using a Green Fluorescent Protein-Glucocorticoid Receptor Chimera that the RAN/TC4 GTPase Mediates an Essential Function Independent of Nuclear Protein Import; Carey et al.; *J Cell Biol*, Vol. 133, pg. 986 (1996).
[23] Presently pending independent claims 44-46 of USSN 10/072,036.